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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/344,526

Applicant(s)
Chee et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 2, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 and 16-35 is/are pending in the application.
- 4a) ☒ Of the above, claim(s) 1-7 and 15 have been canceled. is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14, 16-18, and 21-35 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) 4 sheets
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other

Applicants' arguments, filed 7/2/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16-18 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Ekins et al. (P/N 5,516,635).

This rejection is reiterated and maintained from the previous office action, mailed 2/27/01. Applicants argue that shaking to distribute microspheres would defeat the purpose of Ekins et al. in Example 5. In response it is not seen what is meant by this argument. Shaking clearly would cause the microspheres of Ekins et al. to move about in a random manner

which then would only permit random association onto sites of attachment within the wells. This argument therefore is non-persuasive as random association onto sites as required in the above listed instant claims is clearly the result of shaking in Exkins et al.

Claims 8-14, 16-18, and 21-35 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Walt et al. (P/N 6,023,540).

This rejection is reiterated and maintained from the previous office action, mailed 2/27/01, and as necessitated by amendment regarding newly added claim 35. Applicants argue that optical signatures are utilized in Walt et al. for decoding microspheres. It is noted that the fluorescent dyes of Walt et al. are attached to via binding to the microspheres and thus the microspheres per se do not have a fluorescent or optical signature before this binding. It is thus noted that the microspheres per se in claim 13 do not have an optical signature but have a bound dye. It is also noted that the determining step b) in instant claim 13, for example, does not limit the type of determining that is practiced. Therefore microspheres which are not fluorescent but have attached optical dyes are still usable within the practice of instant claim 13 and also yet rejected based on Walt et al. Applicants further argue that decoding binding ligands are not disclosed per se in Walt et al. In

response this is non-persuasive in that the fluorescent dyes of Walt et al. must bind to binding entities on microspheres and thus decoding binding ligands must be present on the Walt et al. microspheres for this binding to occur. Binding does not occur in a vacuum but requires some sort of ligand binding and thus with the dye practice is clearly a decoding binding ligand disclosure in Walt et al. Regarding newly added claim 35 nucleic acid analyte practice as bioactive agents was discussed in the previous basis for this rejection, mailed 2/27/01.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 8-14, 21, and 23-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al. (P/N 5,516,635).

This rejection is reiterated and maintained from the previous office action, mailed 2/27/01, and as necessitated by amendment regarding newly added claim 35. It is noted that nucleic acid bioactive agents was cited previously in Ekins et al. at column 8, line 39, through column 9, line 22. Applicants argue that the random distribution of microspheres in wells as in Ekins et al. would defeat the invention purpose. In response the surface of each well is deemed a surface whereupon attachment sites for the microspheres are randomly occupied by said microspheres. This clearly is a random type of attachment. Applicants argue that binding between a capture binding agent and a developing binding material is specific in nature. This is acknowledged but does not negate that random association of microspheres over these specific sites in each well. In fact, it directs the Ekins et al. invention to clearly coincide with that of the instant invention which also has specific site for attachment of microspheres. Applicants then argue that random distribution of microspheres does not have a reasonable expectation of success in the Ekins et al. description but fails to indicate what is distinguished over the also random distribution of the instant invention over discrete and specific sites of microsphere attachment. Applicants may be arguing that random distribution over all wells, or that is, between wells in Ekins et al. is a distinguishing feature compared to the instant

invention. In response there is no instant limitation as to what random distribution is meant in the instant claims as to whether it may be random within wells or random between wells. Either type of randomness is a randomness of distribution, only different in extent over the overall array surface. There are no instant claim limitations as to the extent of randomness, but rather only that random distribution of some type is required in the instant claims as is present, for example, in Ekins et al.

It is acknowledged that the following applications have been considered as indicated in the IDS, filed 4/9/01: 09/189,543; 60/090,473; 09/287,573; 08/944,850; 09/315,584; 09/256,943; 60/113,968; 09/151,877; 08/818,199; and 08/851,203.

Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 23, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Flunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

September 28, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER